AUG 1 2 2005

K051932

510(k) SUMMARY

Date of preparation of summary:
4th July 2005

Submitted by:
Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex
RH20 9RR
United Kingdom

Contact name, (application correspondent)**:**
Peter Stegagno, Director, Regulatory Affairs & Quality Assurance
4775 Peachtree Industrial Boulevard, Building 300, Suite 300
Norcross, Georgia, 30092
USA

Email: peter.stegagno@elekta.com
Telephone: (770) 300 9725 x2548 Fax: (770) 448 6338

Trade Name:..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Common Name: Medical Linear Accelerator (with Patient Imaging)

Classification Name: Medical Linear Accelerator Accessory 90 IYE

Predicate Device: Elekta Synergy® System (K032996)

Product Description:
This Premarket Notification Special 510(k) describes modifications to the Elekta Synergy® System; a combination of the specially prepared Elekta medical linear accelerator, Elekta Synergy® Platform, with the XVI on-board kV imaging accessory. The primary reasons for the modifications to this product are to provide:

- Hardware & software support for increased patient throughput
- Easier selection of parameters & provision of clinical presets to improve efficiency
- Improved image quality and image management
- Improved tools for device set-up and image processing
- Improved connectivity with other systems through DICOM

Intended Use Statement:
This is unchanged from the predicate device and is defined as;
"The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5
are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner."

Summary of Technological Characteristics:
The Elekta Synergy® and Elekta Synergy® S comprise a standard Elekta medical linear accelerator, modified to accept the fitting of a kV imaging system (XVI R3.5), with a common MV and kV isocentre and orthogonal beam paths, all as previously cleared under Control Number K032996.

There has been no change made to the underlying technological characteristics of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Elekta Limited
% Mr. Peter Stegagno
Director, Regulatory Affairs
& Quality Assurance
Elekta, Inc.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K051932
Trade/Device Name: Elekta Synergy®, Elekta Synergy® S and XVI R3.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 8, 2005
Received: July 13, 2005

Dear Mr. Stegagno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051932

Device Name ..... Elekta Synergy®, Elekta Synergy® S, and XVI R3.5

Indication for Use: The Elekta Synergy®, Elekta Synergy® S, and XVI R3.5 are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed physician.

Prescription Use - YES ~~AND~~/OR Over-The-Counter Use - NO
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051932

Elekta Limited, Fleming Way, Crawley, West Sussex, RH10 9RR UK +44 1293 544422 Fax: +44 1293 654321